

CLAIMS

We claim:

1. An apparatus for treating tissue near a valve to modify flow through the valve, comprising:
 - a cinching member having a central region and at least two anchoring regions on opposing ends of the central region,
 - the cinching member being configured for delivery through a catheter to the tissue whereby the cinching member has a first shape during the delivery and a second shape after the delivery.
2. The apparatus of claim 1 wherein the tissue comprises an annulus of cardiac tissue surrounding the valve.
3. The apparatus of claim 1 wherein the valve comprises a cardiac valve.
4. The apparatus of claim 1 wherein the central region comprises a continuous alternating length.
5. The apparatus of claim 1 wherein each of the anchoring regions comprise a fastener.
6. The apparatus of claim 1 further comprising a plurality of additional cinching members, the cinching members being interwoven such that a plurality of spaces are defined therebetween in the second shape.
7. The apparatus of claim 1 further comprising a biocompatible fastener for attaching each of the anchoring regions to the tissue.
8. The apparatus of claim 7 wherein the biocompatible fastener comprises a distal end and a proximal end, the proximal end defining a projection for

securing the anchoring region, and the distal end being configured for attachment to the tissue.

9. The apparatus of claim 8 wherein the projection comprises an eyelet.

10. The apparatus of claim 8 wherein the anchoring region is secured to the projection via a mechanical fastener selected from the group consisting of sutures, adhesives, welds, hooks, and clips.

11. The apparatus of claim 8 wherein the distal end comprises a fixation device selected from the group consisting of sutures, adhesives, barbs, screws, pivoting locks, hooks, clips, and tags.

12. The apparatus of claim 1 wherein the cinching member is configured to approximate a portion of periphery defined by the valve, the central region comprising an arcuate length whereby each of the anchoring regions is in apposition to each other.

13. The apparatus of claim 12 wherein the portion of the periphery approximated by the cinching member comprises at least about 50%.

14. The apparatus of claim 13 wherein the portion of the periphery approximated by the cinching member comprises about 50% to 75%.

15. The apparatus of claim 12 wherein each of the anchoring regions is biased towards the central region.

16. The apparatus of claim 1 wherein the cinching member comprises a biocompatible material selected from the group consisting of shape memory alloys and superelastic alloys.

17. The apparatus of claim 16 wherein the shape memory alloy comprises Nickel-Titanium alloy.

18. The apparatus of claim 1 wherein the cinching member is at least partially coated with a coating layer.

19. The apparatus of claim 18 wherein the coating layer comprises a therapeutic agent.

20. The apparatus of claim 18 wherein the coating layer is hydrophilic.

21. The apparatus of claim 19 wherein the therapeutic agent comprises an anti-thrombosis agent.

22. The apparatus of claim 18 wherein the coating layer comprises a radiopaque layer.

23. The apparatus of claim 22 wherein the radiopaque layer is selected from the group consisting of Nickel-Titanium alloy, Platinum, Palladium, Gold, and Tantalum.

24. The apparatus of claim 1 wherein the central region defines a first plane and the anchoring regions define a second plane, the second plane defining an angle relative to the first plane.

25. The apparatus of claim 24 wherein the central region is configured to lie over a periphery of the valve.

26. The apparatus of claim 24 wherein the angle is about 60° to 120°.

27. The apparatus of claim 24 wherein the angle is about 90°.

28. The apparatus of claim 24 wherein the central region comprises a shape selected from the group consisting of semi-circles, arcs, half-ellipses, triangles, rectangles, and loops.

29. The apparatus of claim 1 wherein each of the anchoring regions are configured to pierce tissue.

30. The apparatus of claim 29 wherein each of the anchoring regions comprise a shape selected from the group consisting of semi-circles, triangles, arcs, half-ellipses, hooks, and V-shapes.

31. The apparatus of claim 29 wherein each of the anchoring regions is selected from the group consisting of barbs, screws, pivoting locks, clips, and tags.

32. The apparatus of claim 1 wherein the first shape comprises a geometric shape selected from the group consisting of U shapes and V shapes.

33. The apparatus of claim 1 wherein the catheter comprises an elongate tubular member having a distal end and a proximal end with a lumen therebetween, the distal end defining a delivery port configured to pass the cinching member therethrough.

34. The apparatus of claim 33 wherein the catheter further comprises a stylet having a distal end and a proximal end with a length therebetween, the stylet being slidably disposed in the lumen and being manipulatable from its proximal end.

35. The apparatus of claim 34 wherein the stylet distal end is angled.

36. The apparatus of claim 34 wherein the catheter further comprises a linear advancement mechanism connected to the proximal end of the stylet.

37. The apparatus of claim 36 wherein the linear advancement mechanism is selected from the group consisting of thumb-slides, screws, ratchets, and gears.

38. The apparatus of claim 33 wherein the catheter further comprises a radiopaque tip disposed on the distal end of the elongate tubular member.

39. The apparatus of claim 38 wherein the radiopaque tip comprises a metal selected from the group consisting of Nickel-Titanium alloy, Platinum, Palladium, Gold, and Tantalum.

40. The apparatus of claim 38 wherein the radiopaque tip defines a lumen therethrough in communication with the elongate tubular member.

41. The apparatus of claim 33 wherein the catheter further comprises a liner disposed in the lumen proximal of the distal end.

42. The apparatus of claim 41 wherein the liner comprises a material selected from the group consisting of shape memory alloys and superelastic alloys.

43. The apparatus of claim 33 wherein the catheter further comprises a device disposed on the distal end, the device being selected from the group consisting of sensors and transducers.

44. The apparatus of claim 43 wherein the sensor is of a type selected from the group consisting of ultrasound sensors, Doppler, electrodes, and pressure sensors.

45. The apparatus of claim 43 wherein the transducer is configured to deliver energy of a type selected from the group consisting of RF, electrical, and heat energy.

46. The apparatus of claim 43 wherein the sensor is connected to a monitor.

09997216 070304
T03020 312286860

47. A method for treating tissue near a valve to modify flow through the valve, comprising:

providing a cinching member having a central region, a first anchoring region, and a second anchoring region, each of the anchoring regions being attached to opposing ends of the central region;

placing a delivery catheter near the tissue;

urging the cinching member through a distal opening defined in the catheter such that the first anchoring region exits the distal opening and attaches to a first area of the tissue; and

further urging the cinching member through the distal opening such that second anchoring region exits the distal opening and attaches to a second area of the tissue.

48. The method of claim 47 wherein the tissue comprises an annulus of cardiac tissue surrounding the valve.

49. The method of claim 47 wherein the valve comprises a cardiac valve.

50. The method of claim 47 wherein providing a cinching member further comprises providing a plurality of additional cinching members.

51. The method of claim 47 further comprising providing a biocompatible fastener for attaching the first and the second anchoring regions to the first and the second areas of tissue.

52. The method of claim 51 wherein the biocompatible fastener is attached to the first and the second areas of tissue via a fixation device selected from the group consisting of sutures, adhesives, barbs, screws, pivoting locks, hooks, clips, and tags.

53. The method of claim 47 wherein the cinching member is comprised of a shape memory alloy.

54. The method of claim 53 wherein the shape memory alloy comprises Nickel-Titanium alloy.

55. The method of claim 47 wherein the first anchoring region forms a shape configured for attachment to the first area of the tissue upon exiting the distal opening.

56. The method of claim 55 wherein the shape is selected from the group consisting of semi-circles, triangles, arcs, half-ellipses, hooks, and V-shapes.

57. The method of claim 47 wherein the second anchoring region forms a shape configured for attachment to the second area of the tissue upon exiting the distal opening.

58. The method of claim 57 wherein the shape is selected from the group consisting of semi-circles, triangles, arcs, half-ellipses, hooks, and V-shapes.

59. The method of claim 47 wherein the central region forms a shape selected from the group consisting of semi-circles, arcs, half-ellipses, triangles, rectangles, and loops.

60. The method of claim 47 further comprising forming a first plane defined by the central region and forming a second plane defined by the first and the second anchoring regions, the second plane defining an angle relative to the first plane.

61. The method of claim 60 wherein the angle is about 60° to 120°.

62. The method of claim 60 wherein the angle is about 90°.

63. The method of claim 47 wherein the first anchoring region traverses the valve and attaches to the first area of the tissue located opposite of the delivery catheter.

64. The method of claim 47 wherein the second anchoring region attaches to the second area of the tissue located adjacent to the delivery catheter.

65. The method of claim 47 wherein the first area and the second area are located about 180° apart.

66. The method of claim 47 wherein urging the cinching member through the distal opening defined in the catheter comprises advancing a stylet having a distal end and a proximal end with a length therebetween through the delivery catheter to urge the cinching member.

67. The method of claim 66 wherein the stylet distal end is angled.

68. The method of claim 66 wherein the stylet is advanced by a linear advancement mechanism connected at the proximal end of the stylet.

69. The method of claim 68 wherein the linear advancement mechanism is selected from the group consisting of thumb-slides, screws, ratchets, and gears.

70. The method of claim 47 wherein placing the delivery catheter near the tissue comprises visualizing the delivery catheter via a radiopaque tip disposed on a distal end of the delivery catheter.

71. The method of claim 70 wherein the radiopaque tip comprises a metal selected from the group consisting of Nickel-Titanium alloy, Platinum, Palladium, Gold, and Tantalum.

72. The method of claim 47 further comprising sensing the first area or the second area with a device disposed on a distal end of the delivery catheter, the device being selected from the group consisting of sensors and transducers.

73. The method of claim 72 wherein the sensor is of a type selected from the group consisting of ultrasound sensors, Doppler, electrodes, and pressure sensors.

74. The method of claim 47 further comprising delivering energy to the first area or the second area with a transducer disposed on a distal end of the delivery catheter.

75. The method of claim 74 wherein the energy is of a type selected from the group consisting of RF, electrical, and heat energy.

09898726-070304
T03020-92786860

76. A system for treating tissue near a valve to modify flow through the valve, comprising:

a first catheter having a distal end region, the catheter being configured for transluminal delivery of the end region to the target site;

an end effector in communication with the distal end region, the end effector being configured to transfer energy to the tissue at the target site to induce thermal shrinkage of collagen in the tissue, thereby modifying flow through the valve; and

a cinching member having a central region and at least two anchoring regions on opposing sides of the central region, the cinching member being configured for delivery through the first catheter or a second catheter to the tissue whereby the cinching member has a first shape during the delivery and a second shape after the delivery.

77. The system of claim 76, wherein the tissue comprises an annulus of tissue surrounding a cardiac valve.

78. The system of claim 77, wherein modifying flow through the valve comprises reducing a circumference of the cardiac valve.

79. The system of claim 78, wherein the tissue comprises a support structure of a cardiac valve.

80. The system of claim 79, wherein the support structure is chosen from the group consisting of a chordae tendineae and a papillary muscle.

81. The system of claim 80, wherein modifying flow through the valve comprises shortening the chordae tendineae to properly align leaflets of the valve.

82. The system of claim 76, wherein the tissue at the target site comprises a leaflet of a cardiac valve.

83. The system of claim 76 further comprising a plurality of additional cinching members, the cinching members being interwoven such that a plurality of spaces are defined therebetween in the second shape.

84. The system of claim 76 further comprising a biocompatible fastener for attaching each of the anchoring regions to the tissue.

85. The system of claim 76 wherein the cinching member is configured to approximate a portion of periphery defined by the valve, the central region comprising an arcuate length whereby each of the anchoring regions is in apposition to each other.

86. The system of claim 85 wherein the portion of the periphery approximated by the cinching member comprises at least about 50%.

87. The system of claim 86 wherein the portion of the periphery approximated by the cinching member comprises about 50% to 75%.

88. The system of claim 85 wherein each of the anchoring regions is biased towards the central region.

89. The system of claim 76 wherein the cinching member comprises a biocompatible material selected from the group consisting of shape memory alloys and superelastic alloys.

90. The system of claim 89 wherein the shape memory alloy comprises Nickel-Titanium alloy.

91. The system of claim 76 wherein the central region defines a first plane and the anchoring regions define a second plane, the second plane defining an angle relative to the first plane.

92. The system of claim 91 wherein the angle is about 60° to 120°.

93. The system of claim 91 wherein the angle is about 90°.

94. The system of claim 91 wherein the central region comprises a shape selected from the group consisting of semi-circles, arcs, half-ellipses, triangles, rectangles, and loops.

95. The system of claim 76 wherein each of the anchoring regions are configured to pierce the tissue.

96. The system of claim 95 wherein each of the anchoring regions comprise a shape selected from the group consisting of semi-circles, triangles, arcs, half-ellipses, hooks, and V-shapes.

97. The apparatus of claim 95 wherein each of the anchoring regions is selected from the group consisting of barbs, screws, pivoting locks, clips, and tags.